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Re-evaluation Note REV2016-18

Special Review of Diazinon - Subsection 17(1) of *Pest Control Products Act*: Proposed Decision for Consultation

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1.0 Introduction

The Pest Management Regulatory Agency (PMRA) has initiated a special review of diazinon under subsection 17(1) of the *Pest Control Products Act* based on the toxicology information submitted under section 12 of the *Pest Control Products Act*, following the re-evaluation of diazinon (Canada, 2009; Canada, 2016).

As required by subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern that prompted the special review of pest control products containing diazinon.

2.0 Uses of Diazinon in Canada

Diazinon is an organophosphate insecticide with acetylcholinesterase inhibition activity. Diazinon is registered for cattle ear tags and as a soil drench application on blackberry, loganberry, raspberry, onion, rutabaga and turnip. All currently registered pest control products containing diazinon (Appendix I) are considered in this special review.

All seed treatment, foliar and granular uses of diazinon were cancelled as part of the re-evaluation decision (Canada, 2009). The last date of use for these uses is December 31, 2016. These uses have not been considered in the special review.

3.0 Aspects of Concern that Prompted the Special Review

The PMRA reviewed information submitted under Section 12 of the *Pest Control Products Act* (Appendix II) following the re-evaluation, and re-assessed the existing toxicological database for diazinon. The findings of the comparative cholinesterase and developmental neurotoxicity studies confirmed that inhibition of brain and erythrocyte cholinesterase activities were the most sensitive toxicological effects. Furthermore, the studies indicated sensitivity of the young to cholinesterase inhibition.

Based on the reassessed database, new diazinon toxicological endpoints for dermal exposure have been established (Appendix III). The revised toxicological endpoints for dermal risk assessment affect the existing occupational assessment (Canada, 2009). Consequently, the following aspects of concerns are identified for the special review under subsection 17(1) of the *Pest Control Products Act*:

- Potential risk to workers mixing/loading/applying;
- Potential risk to postapplication workers.

Endpoints for characterization of potential dietary risks are higher than the existing risk assessment, whereas endpoints for inhalation risk assessment remained the same. No update to the dietary assessment is required.

Regarding the *Pest Control Products Act* factor, the toxicity data are considered complete. Based on the nature and level of concern for the cholinesterase endpoint and the fact that, for certain risk assessments, the endpoint was established from data on the sensitive subpopulation, the *Pest Control Products Act* factor is reduced to 1-fold.

4.0 PMRA Evaluation of the Aspects of Concern that Prompted the Special Review

Following the initiation of the special review of diazinon, the PMRA requested information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. No information was received related to the aspects of concern.

In order to evaluate the aspects of concern for diazinon, the PMRA has considered currently available relevant scientific information, which includes information considered for the re-evaluation, and information submitted under section 12 of the *Pest Control Products Act* following the re-evaluation (Appendix II). No information related to the aspects of concern was identified in the Canadian incident report database.

4.1 Potential Risk to Workers Mixing/Loading/Applying (M/L/A)

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies (Appendix III) to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

4.1.1 Potential Risk to Workers (M/L/A) from Field Applications (Soil Drench)

Diazinon, as a soil drench, can be applied once for onion, blackberry, loganberry and raspberry (at the early stage of the plant growth cycle) or multiple times for rutabaga and turnip (at different plant growth stages) (Appendix IV). The national production data indicates that the planted areas of these crops are small (AAFC, 2007, 2012(a) and 2012(b)). Based on the above, exposure of workers mixing, loading and applying diazinon, as a soil drench, is expected to be of a short-term duration and to occur via both dermal and inhalation routes. In turn, the following potential exposure scenarios are identified for the current conditions of use:

- Mixing/loading of wettable powder in water soluble packaging with workers wearing a long-sleeved shirt, long pants, socks, shoes, and chemical-resistant gloves;
- Mixing/loading of emulsifiable concentrates using a closed mechanical transfer loading system with workers wearing a long-sleeved shirt, long pants, socks, shoes, and chemical-resistant gloves;
- Mixing/loading of emulsifiable concentrates using an open mechanical transfer loading system with workers wearing chemical resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and footwear, and a NIOSH-approved respirator; and
- Applying to onion, rutabaga, turnip, blackberry, loganberry and raspberry by soil drench groundboom equipment with a closed cab with workers wearing a long-sleeved shirt, long pants, socks and shoes.

Dermal and inhalation exposures were combined because these exposures occur simultaneously and they have a common toxicological endpoint (cholinesterase inhibition). Combined (dermal and inhalation) handler exposure doses were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. Details of the assumptions and calculations are presented in Appendix V.

The target MOE of 100 was not met for most of the assessed scenarios (MOEs = 17-90), when the personal protective equipment (PPE) as stated on the current label was considered. However, the identified risks can be mitigated with additional PPE and by limiting the amount of active ingredient handled per day (MOEs = 100-549; Appendix V), except for emulsifiable concentrates, with an open mechanical transfer loading system. The proposed risk reduction measures to minimize exposure to workers are presented in Appendix VII.

4.1.2 Potential Risk to Workers from Applying Ear Tags to Cattle

Ear tags are applied once a year and are handled by using an ear tag application tool. Tags are removed at the end of the season and before slaughter. Ear tags are impregnated plastic designed as slow release generators. Considering the low frequency of application, the design of the product (as a slow release of diazinon), and the current label requirement to wear chemical-resistant gloves when handling the tag, potential worker exposure is expected to be minimal. On this basis, the potential risk to workers handling ear tags is not of concern and no mitigation measures are proposed for this scenario.

4.2 Potential Risk to Postapplication Workers

There is a potential for postapplication exposure of agricultural workers re-entering sites, treated with diazinon, to conduct agricultural activities. To protect workers involved in postapplication activities, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can enter the field to conduct hand labour following pesticide application. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures below the level of concern.

For these workers, dermal exposure is considered to be the primary route of exposure. Considering the low volatility of this active ingredient (1.4×10^{-4} mm Hg) relative to the NAFTA criterion for a waiver of inhalation exposure data for outdoor uses (NAFTA, 1999), and the current label directions which include REIs, inhalation exposure to diazinon is not expected to be of concern for postapplication workers re-entering treated sites.

For onion, following a single soil drench application at planting and soil incorporation, residues on onion plants are expected to be negligible and thus, soil contact is the most likely exposure scenario for postapplication workers. For berries, following a single application in the early spring at the time when new canes reach 10 cm height, residues on berry canes are expected to also be negligible. Considering that larvae of raspberry crown borers usually locate at crown areas and/or under the soil surface, scouters usually dig up and cut through crowns using tools to look for larvae. It should also be noted that most varieties of blackberries, loganberries and raspberries have prickles and thus, it is reasonably expected that gloves are commonly used in these fields. Therefore, soil contact is considered as the major route of exposure and the

likelihood of plant (cane) contact with bare hands is considered to be unlikely. Given the timing of application of diazinon, harvesting activities are not considered for onion and berries. For rutabaga and turnip, diazinon can be applied at early growth season for control of larvae of root maggots, followed by weekly applications 5-6 weeks after the second application for control of adult root maggot. Considering possible multiple application of diazinon to rutabaga and turnip, thinning, hand weeding, handset irrigation and hand harvesting are considered as likely exposure scenarios. Consequently, the following potential postapplication exposure scenarios are considered as part of the special review:

- Onion: scouting with potential contact with soil.
- Blackberry, loganberry and raspberry: scouting with potential contact with soil.
- Rutabaga and turnip: scouting, thinning, hand weeding, handset irrigation and hand harvesting with potential contact with soil, seedlings, leaves and stems.

The postapplication risk assessment is summarized in Appendix VI.

Onion: Potential dermal exposure of workers to diazinon from soil contact during scouting was not of concern. No additional mitigation measures are proposed.

Blackberry, Loganberry and Raspberry: Potential dermal exposure of workers to diazinon from soil contact during scouting was not of concern. The use of gloves (as described above) is expected to further limit the potential exposure to diazinon for these crops. No additional mitigation measures are proposed.

Rutabaga and Turnip: The PMRA calculated daily dermal exposure estimates for postapplication agricultural workers using default dislodgeable foliar residue (DFR) assumptions. Additional inputs included transfer coefficient (TC) values from studies conducted by the Agricultural Re-Entry Task Force (ARTF), an 8-hour work day, 50% dermal absorption, and an average worker body weight of 80 kg.

In rutabaga and turnip, diazinon is used for the control of root maggot larvae and adults.

For control of root maggot larvae using 1-2 applications at seedling stage, the calculated REIs needed to mitigate potential risks to postapplication workers are 15, 25 and 45 days for thinning/hand weeding, foliar-contact scouting, and handset irrigation, respectively. This is an increase from the existing REI of 4 days on the current label. As the monitoring for disease pressure can also be done by using yellow pan traps and visual scouting, which results in no contact with foliage of rutabagas and turnips, potential exposure during non-foliar contact scouting is expected to be negligible for such activity. On this basis, a default REI of 12 hours would apply for non-foliar contact scouting (Appendix VII).

For control of root maggot adult at the stage when foliage is developed, the calculated REIs needed to mitigate potential risks to postapplication workers are 10, 20, 40 and 36 days for hand weeding, plant-contact scouting, handset irrigation and hand harvesting, respectively. These REIs may not be agronomically feasible due to the timing of application relative to the activities. Therefore, use of diazinon for the control of root maggot adults is proposed for cancellation (Appendix VII)

5.0 Proposed Special Review Decision for Diazinon

Evaluation of available scientific information related to the aspects of concern, indicated that the registered products containing diazinon do not pose unacceptable risk to human health and the environment with the proposed mitigation measures. On this basis, the PMRA is proposing to confirm the current registration of products containing diazinon for sale and use in Canada with the proposed risk mitigation measures pursuant to subsection 21(1) of the *Pest Control Product Act*.

This proposed special review decision is a consultation document[1]. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

6.0 Next Steps

Before making a special review decision on diazinon, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on diazinon. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I. Registered Products Containing Diazinon as of 28 October 2016

Registration Number	Marketing Class	Registrant	Product Name	Guarantee
11889	Commercial	Loveland Products Canada Inc.	Diazinon 500 E	Diazinon 500 g/L
15921	Commercial	Adama Agricultural Solutions Canada Ltd.	Diazol 50 EC	Diazinon 50%
20963	Technical	Adama Agricultural Solutions Canada Ltd.	Diazol Technical	Diazinon 94%
20964	Manufacturing Concentrate	Adama Agricultural Solutions Canada Ltd.	Diazol Oil Manufacturing Concentrate	Diazinon 87%
23004	Commercial	Vétoquinol N.-A. Inc.	Protector Ear Tags	Diazinon 20%
24438	Commercial	Vétoquinol N.-A. Inc.	Eliminator Ear Tags	Cypermethrin 6% Diazinon 11%
25334	Commercial	Y-Tex Corporation	Optimizer Insecticide Cattle Ear Tag	Diazinon 21%
27538	Commercial	Interprovincial Cooperative Limited	Diazinon 50 EC Insecticide	Diazinon 50%
29976	Commercial	Loveland Products Canada Inc.	Diazinon 50 WSP Insecticide	Diazinon 50%

Appendix II. Developmental Neurotoxicity and Additional Comparative Cholinesterase Studies Submitted by the Registrant under Section 12 of the *Pest Control Products Act*

Following the re-evaluation of diazinon, the PMRA received the following studies under section 12 of the *Pest Control Products Act* (Canada, 2009).

PMRA Document Number	Study Title
2071811	Diazinon: Gestation Day 20 Cholinesterase Determinations in a Dietary Range-finding Developmental Neurotoxicity Study in Rats. Huntingdon Life Sciences, East Millstone, New Jersey. Laboratory report number: 01-4531. Study report date: November 13th, 2002.
2071813 2071818	Diazinon: A Dietary Range-finding Developmental Neurotoxicity Study in Rats. Huntingdon Life Sciences, East Millstone, New Jersey. Laboratory report number: 01-4530, Study report date: November 13th, 2002.
2071816 2071817	Diazinon: A Developmental Neurotoxicity Study in Rats. Huntingdon Life Sciences, East Millstone, New Jersey. Laboratory study number: 01-4532. Study report date: November 17th, 2003.
2147343	Relative Sensitivity of Neonatal/Juvenile and Young Adult CD Rats After an Acute Exposure to Diazinon. Center for Life Sciences and Toxicology, RTI International, Research Triangle Park, North Carolina, Laboratory project number: 08882.4. Study report date: December 23rd, 2003.
2147346	Comparative Sensitivity of Neonatal/Juvenile and Young Adult CD Rats After Repeated Exposure to Diazinon. Center for Life Sciences and Toxicology, RTI International, Research Triangle Park, North Carolina. Laboratory project number: 08882.005. Study report date: December 23rd, 2003.

Appendix III. Diazinon Endpoints for Human Health Risk Assessment

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	CAF or MOE[a]
Acute Dietary	$BMDL_{10}$ = 1.462 mg/kg bw (PND11 pups)	Depressed BChE activity	Acute cholinesterase study - Rat	100
	ARfD = 0.015 mg/kg bw			
Chronic Dietary	$BMDL_{20}$ = 0.4849 mg/kg bw/day (pups exposed from PND11 to PND17)	Depressed EChE activity	7-day repeat-dose cholinesterase study - Rat	300
	ADI = 0.0016 mg/kg bw/day			
Short-term Dermal[b]	$BMDL_{20}$ = 0.2784 mg/kg bw/day (GD20 dams)	Depressed EChE activity	Developmental cholinesterase study - Rat	100
Intermediate-and Long-term Dermal[b]	$BMDL_{20}$ = 0.2784 mg/kg bw/day (GD20 dams)	Depressed EChE activity	Developmental cholinesterase study - Rat	300
Short-, Intermediate- and Long-term Inhalation	NOAEL = 0.026 mg/kg bw/day	Depressed BChE and EChE activity	21-day Inhalation Study - Rat	100
Cancer Risk Assessment	Not required			

[a] CAF (composite assessment factor) refers to total of uncertainty and *PCPA* factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments

[b] Since an oral point of departure was selected, a dermal absorption factor of 50% was used in route-to-route extrapolation.

Appendix IV Field Uses of Diazinon Considered

Crop	Formulation	Guarantee (g a.i./L or g a.i./kg product)	Application Method	Application timing	Maximum number of applications	Application Interval (days)	Application Rate (kg a.i./ha)	Restricted Entry Interval (days)	PHI (days)
Blackberry, Loganberry, Raspberry	Emulsifiable concentrate (EC)/water soluble pouches (WSP)	500	Apply as a drench to the crown area, by groundboom	At the time when new canes reach 10 cm height	1	N/A	2.0 or 2.205	6	Not applicable – do not apply after bloom
Onion	EC/WSP	500	Apply in sufficient water to drench the seed furrow, by groundboom	At planting or sowing time	1	N/A	1.1 or 2.25	3	10
Rutabaga, Turnip	EC	500	Soil drench by groundboom	For control of root maggot larvae, 1st application: At the time when seedling are up; 2nd application: after thinning. For control of root maggot adults, make weekly application as a drench 5-6 weeks after the 2nd application.	Not stated (1 to 2 for control of larvae – see application instructions) (1+ for control of adult flies)	5-6 weeks	1st and/or 2nd application: 1.1; and/or weekly application 0.54 or 0.55.	4	14

Appendix V. Mixing/Loading/Applying Exposure Estimates and Margins of Exposure (MOE)

Crop	Applicator	Form[a]	Application Type/ Equipment	Application Rates (kg a.i./ha)	Area treated per day (ha)[b]	a.i. handled per day (kg)	Dermal				Inhalation				Total systemic exposure (µg/kg bw/day)	Margins of Exposure		
							Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[d]	Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[c]		Dermal[f]	Inhalation[g]	Combined[h]
							M/L	App	Total		M/L	App	Total					
Estimated exposure resulting from mixing/loading/applying products containing diazinon following current label requirements																		
Wettable powder in water soluble packaging; Mixers/loaders must wear a long-sleeved shirt and long pants, socks and shoes and chemical-resistant gloves; Applicators using groundboom equipment with a closed cab must wear a long-sleeved shirt, long pants, socks and shoes. (Parameters obtained from the PHED[j] Scenario 6a for Mixing/Loading and Scenario 12 for Applying)																		
Onion	Farmer	WSP	groundboom soil drench	1.100	5	5.5	21.61	11.05	32.66	1.123	0.18	0.06	0.24	0.01650	1.14	248	1576	214
Onion	Farmer	WSP	groundboom soil drench	2.250	5	11.3	21.61	11.05	32.66	2.296	0.18	0.06	0.24	0.03375	2.33	121	770	105
Blackberry, loganberry, raspberry	Farmer	WSP	groundboom soil drench	2.205	5	11.0	21.61	11.05	32.66	2.250	0.18	0.06	0.24	0.03308	2.28	124	786	107
Onion	Custom applicator	WSP	groundboom soil drench	1.100	26	28.6	21.61	11.05	32.66	5.838	0.18	0.06	0.24	0.08580	5.92	48	303	41
Onion	Custom applicator	WSP	groundboom soil drench	2.250	26	58.5	21.61	11.05	32.66	11.941	0.18	0.06	0.24	0.17550	12.12	23	148	20
Blackberry, loganberry, raspberry	Custom applicator	WSP	groundboom soil drench	2.205	26	57.3	21.61	11.05	32.66	11.702	0.18	0.06	0.24	0.17199	11.87	24	151	21
Emulsifiable concentrate; Closed mechanical transfer loading system; Mixers/loaders must wear a long-sleeved shirt and long pants, socks and shoes and chemical-resistant gloves; Applicators using groundboom equipment with a closed cab must wear a long-sleeved shirt, long pants, socks and shoes. (Parameters obtained from the PHED [k] Scenario 4 for Mixing/Loading and Scenario 12 for Applying)																		
Rutabaga, Turnip	Farmer	EC	groundboom soil drench	1.100	5	5.5	18.95	11.05	30.00	1.031	0.11	0.06	0.17	0.01169	1.04	270	2225	240
Onion	Farmer	EC	groundboom soil drench	1.100	5	5.5	18.95	11.05	30.00	1.031	0.11	0.06	0.17	0.01169	1.04	270	2225	240
Onion	Farmer	EC	groundboom soil drench	2.250	5	11.3	18.95	11.05	30.00	2.109	0.11	0.06	0.17	0.02391	2.13	132	1088	118
Blackberry, loganberry, raspberry	Farmer	EC	groundboom soil drench	2.205	5	11.0	18.95	11.05	30.00	2.067	0.11	0.06	0.17	0.02343	2.09	134	1110	120
Rutabaga, Turnip	Custom applicator	EC	groundboom soil drench	1.100	26	28.6	18.95	11.05	30.00	5.363	0.11	0.06	0.17	0.06078	5.42	52	428	46
Onion	Custom applicator	EC	groundboom soil drench	1.100	26	28.6	18.95	11.05	30.00	5.363	0.11	0.06	0.17	0.06078	5.42	52	428	46

Crop	Applicator	Form[a]	Application Type/ Equipment	Application Rates (kg a.i./ha)	Area treated per day (ha)[b]	a.i. handled per day (kg)	Dermal				Inhalation				Total systemic exposure (µg/kg bw/day)	Margins of Exposure		
							Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[d]	Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[c]				
							M/L	App	Total		M/L	App	Total			Dermal[f]	Inhalation[g]	Combined[h]
Onion	Custom applicator	EC	groundboom soil drench	2.250	26	58.5	18.95	11.05	30.00	10.969	0.11	0.06	0.17	0.12431	11.09	25	209	23
Blackberry, loganberry, raspberry	Custom applicator	EC	groundboom soil drench	2.205	26	57.3	18.95	11.05	30.00	10.749	0.11	0.06	0.17	0.12183	10.87	26	213	23
Emulsifiable concentrate; Open mechanical transfer loading system; Mixers/loaders must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear and a NIOSH-approved respirator; Applicators using groundboom equipment with a closed cab must wear a long-sleeved shirt, long pants, socks and shoes. (Parameters obtained from the PHED [k] Scenario 3a for Mixing/Loading and Scenario 12 for Applying)																		
Rutabaga, Turnip	Farmer	EC	groundboom soil drench	1.100	5	5.5	29.09	11.05	40.14	1.380	0.16	0.06	0.22	0.01513	1.39	201	1719	180
Onion	Farmer	EC	groundboom soil drench	1.100	5	5.5	29.09	11.05	40.14	1.380	0.16	0.06	0.22	0.01513	1.39	201	1719	180
Onion	Farmer	EC	groundboom soil drench	2.250	5	11.3	29.09	11.05	40.14	2.822	0.16	0.06	0.22	0.03094	2.85	98	840	88
Blackberry, loganberry, raspberry	Farmer	EC	groundboom soil drench	2.205	5	11.0	29.09	11.05	40.14	2.766	0.16	0.06	0.22	0.03032	2.80	101	858	90
Rutabaga, Turnip	Custom applicator	EC	groundboom soil drench	1.100	26	28.6	29.09	11.05	40.14	7.175	0.16	0.06	0.22	0.07865	7.25	39	331	35
Onion	Custom applicator	EC	groundboom soil drench	1.100	26	28.6	29.09	11.05	40.14	7.175	0.16	0.06	0.22	0.07865	7.25	39	331	35
Onion	Custom applicator	EC	groundboom soil drench	2.250	26	58.5	29.09	11.05	40.14	14.676	0.16	0.06	0.22	0.16088	14.84	19	162	17
Blackberry, loganberry, raspberry	Custom applicator	EC	groundboom soil drench	2.205	26	57.3	29.09	11.05	40.14	14.383	0.16	0.06	0.22	0.15766	14.54	19	165	17
Mitigation for scenarios which do not pass (MOEs < the target MOE of 100) - by increasing Mixing/loading PPE level to the maximum, increasing Applying PPE to coveralls in the closed cab (not chemical resistant overalls) and reducing chemical handled per day																		
Wettable powder in water soluble packaging; Mixers/loaders must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear; Applicators using groundboom equipment with a closed cab must wear coveralls over a long-sleeved shirt and long pants, socks and shoes. (Parameters obtained from the PHED [k] Scenario 6a for Mixing/Loading and Scenario 12 for Applying)																		
Onion	Farmer	WSP	groundboom soil drench	1.100	5	5.5	5.18	4.42	9.60	0.33	0.18	0.06	0.24	0.02	0.35	842	1576	549
Onion	Farmer	WSP	groundboom soil drench	2.250	5	11.3	5.18	4.42	9.60	0.68	0.18	0.06	0.24	0.03	0.71	412	770	268
Blackberry, loganberry, raspberry	Farmer	WSP	groundboom soil drench	2.205	5	11.0	5.18	4.42	9.60	0.66	0.18	0.06	0.24	0.03	0.69	420	786	274

Crop	Applicator	Form[a]	Application Type/ Equipment	Application Rates (kg a.i./ha)	Area treated per day (ha)[b]	a.i. handled per day (kg)	Dermal				Inhalation				Total systemic exposure (µg/kg bw/day)	Margins of Exposure		
							Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[d]	Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[e]		Dermal[f]	Inhalation[g]	Combined[h]
							M/L	App	Total		M/L	App	Total					
Onion	Custom applicator	WSP	groundboom soil drench	1.100	26	28.6	5.18	4.42	9.60	1.716	0.18	0.06	0.24	0.08580	1.80	162	303	106
Onion	Custom applicator	WSP	groundboom soil drench	2.250	13.4[c]	30.2	5.18	4.42	9.60	1.809	0.18	0.06	0.24	0.09045	1.90	154	287	100
Blackberry, loganberry, raspberry	Custom applicator	WSP	groundboom soil drench	2.205	13.6[c]	30.0	5.18	4.42	9.60	1.799	0.18	0.06	0.24	0.08996	1.89	155	289	101
Emulsifiable concentrate; Closed mechanical transfer loading system; Mixers/loaders must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear; Applicators using groundboom equipment with a closed cab must wear coveralls over a long-sleeved shirt and long pants, socks and shoes. (Parameters obtained from the PHED [k] Scenario 4 for Mixing/Loading and Scenario 12 for Applying)																		
Rutabage, Turnip	Farmer	EC	groundboom soil drench	1.100	5	5.5	7.74	4.42	12.16	0.42	0.11	0.06	0.17	0.01	0.43	665	2225	512
Onion	Farmer	EC	groundboom soil drench	1.100	5	5.5	7.74	4.42	12.16	0.42	0.11	0.06	0.17	0.01	0.43	665	2225	512
Onion	Farmer	EC	groundboom soil drench	2.250	5	11.3	7.74	4.42	12.16	0.86	0.11	0.06	0.17	0.02	0.88	325	1088	250
Blackberry, loganberry, raspberry	Farmer	EC	groundboom soil drench	2.205	5	11.0	7.74	4.42	12.16	0.84	0.11	0.06	0.17	0.02	0.88	332	1110	255
Rutabage, Turnip	Custom applicator	EC	groundboom soil drench	1.100	26	28.6	7.74	4.42	12.16	2.174	0.11	0.06	0.17	0.06078	2.23	128	428	98[i]
Onion	Custom applicator	EC	groundboom soil drench	1.100	26	28.6	7.74	4.42	12.16	2.174	0.11	0.06	0.17	0.06078	2.23	128	428	98[i]
Onion	Custom applicator	EC	groundboom soil drench	2.250	12.5[c]	28.1	7.74	4.42	12.16	2.138	0.11	0.06	0.17	0.05977	2.20	130	435	100
Blackberry, loganberry, raspberry	Custom applicator	EC	groundboom soil drench	2.205	12.7[c]	28.0	7.74	4.42	12.16	2.128	0.11	0.06	0.17	0.05951	2.19	131	437	101
Emulsifiable concentrate; Open mechanical transfer loading system; Mixers/loaders must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear and a NIOSH-approved respirator; Applicators using groundboom equipment with a closed cab must wear coveralls over a long-sleeved shirt and long pants, socks and shoes. (Parameters obtained from the PHED [k] Scenario 3a for Mixing/Loading and Scenario 12 for Applying)																		
Onion	Farmer	EC	groundboom soil drench	2.250	5	11.3	29.09	4.42	33.51	2.356	0.16	0.06	0.22	0.03094	2.39	118	840	103
Blackberry, loganberry, raspberry	Farmer	EC	groundboom soil drench	2.205	5	11.0	29.09	4.42	33.51	2.309	0.16	0.06	0.22	0.03032	2.34	120	858	106
Rutabage, Turnip	Custom applicator	EC	groundboom soil drench	1.100	10.5[c]	11.6	29.09	4.42	33.51	2.419	0.16	0.06	0.22	0.03176	2.45	115	819	101

Crop	Applicator	Form[a]	Application Type/ Equipment	Application Rates (kg a.i./ha)	Area treated per day (ha)[b]	a.i. handled per day (kg)	Dermal				Inhalation				Total systemic exposure (µg/kg bw/day)	Margins of Exposure		
							Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[d]	Unit Exposure (µg/kg a.i.)			Exposure (µg/kg bw/day)[e]				
							M/L	App	Total		M/L	App	Total			Dermal[f]	Inhalation[g]	Combined[h]
Onion	Custom applicator	EC	groundboom soil drench	1.100	10.5[c]	11.6	29.09	4.42	33.51	2.419	0.16	0.06	0.22	0.03176	2.45	115	819	101
Onion	Custom applicator	EC	groundboom soil drench	2.250	5.1[c]	11.5	29.09	4.42	33.51	2.403	0.16	0.06	0.22	0.03156	2.43	116	824	101
Blackberry, loganberry, raspberry	Custom applicator	EC	groundboom soil drench	2.205	5.2[c]	11.5	29.09	4.42	33.51	2.401	0.16	0.06	0.22	0.03153	2.43	116	825	102

[a] EC = Emulsifiable Concentrate; WSP = Wettable Powder in Water Soluble Packaging.

[b] A default assumption for the area treated per day (ATPD) of 26 ha was used for occupational mixing/loading/applying risk assessment for soil drench groundboom application by custom applicators. Considering the Canadian national production and farm sizes of rutabaga, turnip, onion, blackberry, loganberry and raspberry, an ATPD of 5 ha was used for occupational mixing/loading/applying risk assessment for soil drench groundboom application by farmers (Canadian farm sizes are 3.24, 2.02 and 2.95 hectares at 90th percentile for onion, raspberry, and rutabagas and turnips, respectively. Source: 2011, Census of Agriculture, Statistics Canada, http://www.statcan.gc.ca/eng/ca2011/index).

[c] Reduced area treated per day to limit worker exposure to an acceptable level (i.e., MOE>100).

[d] Where dermal exposure µg/kg/day = unit exposure × area treated × rate)/80 kg bw. A dermal absorption factor of 50% was applied.

[e] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate)/80 kg bw. A 90% protection factor was incorporated to account for the use of respirators.

[f] Based on a $BMDL_{20}$ of 278 µg/kg bw/day and a target dermal MOE of 100. Dermal Margin of Exposure (MOE_D) = NOAEL (µg/kg/day) / Dermal Exposure (µg/kg/day).

[g] Based on a NOAEL of 26 µg/kg bw/day and a target inhalation MOE of 100. Inhalation Margin of Exposure (MOE_I) = NOAEL (µg/kg/day) / Inhalation Exposure (µg/kg/day).

[h] Combined MOE = $1/(1/MOE_{dermal} + 1/MOE_{inhalation})$.

[i] The round-up of the MOE of 98 was to 100 will not result in a health risk of concern.

[j] Daily dermal and inhalation handler doses were calculated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. To estimate exposure for each use scenario, appropriate subsets were created from the mixer/loader and applicator database files of PHED. All data were normalized for kg of active ingredient handled. Exposure estimates are presented on the basis of the best-fit measure of central tendency, i.e., summing the measure of central tendency for each body part which is most appropriate to the distribution of data for that body part.

Appendix VI Postapplication Exposure Estimates, Margins of Exposure (MOE) and Proposed Restricted Entry Intervals

Postapplication Exposure to Diazinon Resulting from Plant Foliar Contact with Current Label Restricted Entry Intervals (Note: Shaded cells indicated scenarios where concerns were identified.)

Crop & Formulation	Form & Application Type (Equipment)	Application Rates (kg a.i./ha)[a]	No. of Applications[b]	Activity[c]	Transfer Coefficient (cm^2/hr)[d]	Activity Duration[e]	DFR at the day of entry ($\mu g/cm^2$)[f]	Systemic Exposure ($\mu g/kg$ bw/day)[g]	Current Label Restricted Entry Intervals (REIs) (days)	Margins of Exposure (MOE)[h]
Rutabaga/Turnip	Soil drench (groundboom)	1.100	1	Thinning, or weeding (hand)	70	8	1.8043	6.31	4	44
Rutabaga/Turnip	Soil drench (groundboom)	1.100	1	Scouting	210	8	1.8043	18.94	4	15
Rutabaga/Turnip	Soil drench (groundboom)	1.100	1	Irrigation (hand set)	1750	8	1.8043	157.87	4	2
Rutabaga/Turnip	Soil drench (groundboom)	1st App: 1.100; 2nd App: 1.100[b]	2	Weeding (hand)	70	8	2.3139	8.10	4	34
Rutabaga/Turnip	Soil drench (groundboom)	1st App: 1.100; 2nd App: 1.100[b]	2	Scouting	210	8	2.3139	24.30	4	11
Rutabaga/Turnip	Soil drench (groundboom)	1st App: 1.100; 2nd App: 1.100[b]	2	Irrigation (hand set)	1750	8	2.3139	202.46	4	1
Rutabaga/Turnip	Drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Weeding (hand)	70	8	1.3613	4.76	4	58
Rutabaga/Turnip	Drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Scouting	210	8	1.3613	14.29	4	19
Rutabaga/Turnip	Drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Irrigation (hand set)	1750	8	1.3613	119.12	4	2
Rutabaga/Turnip	Drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Harvesting, Hand	1100	8	1.3613	74.87	4	4

[a] Label rates expressed in kilograms a.i./hectare.

[b] The number of applications based on the currently registered use pattern. For the weekly application on rutabaga/turnip, up to 4 applications were assessed.

[c] Scouting is a common postapplication practice required for disease management. Planting rutabagas and turnips can start from seeds or seedlings; therefore, thinning may be required but not necessary all the time. Hand weeding may happen; however, the possibility of use is low because cultivation and pre-emergence sprays as well as post-emergence sprays are common weeding management for these two crops. Irrigation is also a possible postapplication activity, however, its frequency is low considering rutabaga or turnip is not a high value crop.

[d] A transfer coefficient (TC) is the amount of treated foliage that a worker contacts while performing a specific activity in for a given duration (usually expressed in units of cm2 per hour). Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document (Last updated – February 26, 2015).

[e] For all postapplication activities, work duration of 8 hours/day is assumed.

[f] Dislodgeable Foliar Residue (DFR) is the amount of pesticide residue ($\mu g/cm^2$) on the surface of treated foliage that is available for transfer onto the skin and clothing of an agricultural worker while conducting regular work activities in the treated area. Peak DFR = Application rate × 25% (based on the PMRA 2012 memorandum "Guidance for Evaluators on Use of Agricultural Dislodgeable Foliar Residue/Turf Transferrable Residue Data and Inputs"). DFR is calculated, at x days after application, where x is the REIs on the current labels.

[g] Dermal exposure = DFR × TC × DA × activity duration / bw. A dermal absorption (DA) factor of 50% was applied. Body weight of 80 kg was used.

[h] The resulting MOE on the current label REI day. Based on the $BMDL_{20}$ of 0.278/kg/day and a dermal target MOE of 100.

Postapplication Exposure to Diazinon Resulting from Plant Contact with Proposed Restricted Entry Intervals (Note: Shaded cells indicated scenarios where concerns were identified.)

Crop & Formulation	Form & Application Type (Equipment)	Application Rates (kg a.i./ha)[a]	No. of Applications[b]	Activity[c]	Transfer Coefficient (cm^2/hr)[d]	Activity Duration (hr)[e]	DFR at the day of entry ($\mu g/cm^2$)[f]	Systemic Exposure ($\mu g/kg$ bw/day)[g]	Margins of Exposure (MOE)[h]	Proposed Restricted Entry Intervals (REIs) (days)[i]
Rutabaga/Turnip	Soil drench (groundboom)	1.100	1	Thinning, or weeding (hand)	70	8	0.7767	2.72	102	12
Rutabaga/Turnip	Soil drench (groundboom)	1.100	1	Scouting	210	8	0.2437	2.56	109	23
Rutabaga/Turnip	Soil drench (groundboom)	1.100	1	Irrigation (hand set)	1750	8	0.0296	2.59	107	43
Rutabaga/Turnip	Soil drench (groundboom)	1st App: 1.100; 2nd App: 1.100[h]	2	Weeding (hand)	70	8	0.7261	2.54	109	15
Rutabaga/Turnip	Soil drench (groundboom)	1st App: 1.100; 2nd App: 1.100[h]	2	Scouting	210	8	0.2532	2.66	105	25
Rutabaga/Turnip	Soil drench (groundboom)	1st App: 1.100; 2nd App: 1.100[h]	2	Irrigation (hand set)	1750	8	0.0308	2.69	103	45
Rutabaga/Turnip	Soil drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Weeding (hand)	70	8	0.7235	2.53	110	10
Rutabaga/Turnip	Soil drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Scouting	210	8	0.2523	2.65	105	20
Rutabaga/Turnip	Soil drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Irrigation (hand set)	1750	8	0.0307	2.68	104	40
Rutabaga/Turnip	Soil drench (groundboom)	1st & 2nd App: 1.100; 3rd & 4th weekly App: 0.550	1+ (assessed 4 applications)	Harvesting, Hand	1100	8	0.0467	2.57	108	36

[a] Label rates expressed in kilograms a.i./hectare.

[b] The number of applications based on the currently registered use pattern. For the weekly application on rutabaga/turnip, up to 4 applications were assessed.
[c] Scouting is a common postapplication practice required for disease management. Planting rutabagas and turnips can start from seeds or seedlings; therefore, thinning may be required but not necessary all the time. Hand weeding may happen; however, the possibility of use is low because cultivation and pre-emergence sprays as well as post-emergence sprays are common weeding management for these two crops. Irrigation is also a possible postapplication activity, however, its frequency is low considering rutabaga or turnip is not a high value crop.
[d] A transfer coefficient (TC) is the amount of treated foliage that a worker contacts while performing a specific activity in for a given duration (usually expressed in units of cm2 per hour). Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document (Last updated – February 26, 2015).
[e] For all postapplication activities, work duration of 8 hours/day is assumed.
[f] Dislodgeable Foliar Residue (DFR) is the amount of pesticide residue (µg/cm^2) on the surface of treated foliage that is available for transfer onto the skin and clothing of an agricultural worker while conducting regular work activities in the treated area. Peak DFR = Application rate × 25% (based on the PMRA 2012 memorandum "Guidance for Evaluators on Use of Agricultural Dislodgeable Foliar Residue/Turf Transferrable Residue Data and Inputs"). DFR is calculated, at x days after application, where x is the day when an MOE ≥100 is determined or the proposed REI.
[g] Dermal exposure = DFR × TC × DA × activity duration / bw. A dermal absorption (DA) factor of 50% was applied. Body weight of 80 kg was used.
[h] The resulting MOE on the recommended REI day. Based on the $BMDL_{20}$ of 0.278/kg/day and a dermal target MOE of 100.
[i] Day at which the dermal exposure results in an MOE ≥100.

Postapplication Exposure to Diazinon Resulting from Soil Contact in the Onion Field

Scenario	Rate (kg a.i./ha)	Fraction a.i. available in upper 1 cm soil	CF (volume to weight conversion-cm^3/g soil)	Concentration in soil (µg a.i./mg soil)[a]	Adherence Factor (mg soil/cm^2-event)[b]	Skin surface area (cm^2)[c]	Dermal absorption factor	Dermal exposure (µg/kg/day)[d]	Margins of Exposure (MOE)[e]	Proposed Restricted Entry Intervals (REIs) (hours)[f]
Commercial workers conducting agricultural activities that have contact with soil of the onion field (primary activity is scouting)	2.25	1	0.67	0.01508	0.5	3300	0.5	0.1555	1788	12
Commercial workers conducting agricultural activities that have contact with soil of the fields planting blackberry, loganberry, raspberry (primary activity is scouting)	2.205	1	0.67	0.01477	0.5	3300	0.5	0.1524	1825	12

[a] Concentration of diazinon in/on soil on the day of application (mg a.i./g soil). Value was estimated using the maximum rate for soil application and the assumption that 100% of the applied diazinon was located within the uppermost 1 cm of soil. Calculated using the following formula: Application rate (kg ai/ha) * fraction of active ingredient in uppermost cm of soil (fraction/cm) assumed to be 100% * volume to weight conversion factor (0.67 cm^3/g soil). This is the same approach as that outlined in the US EPA Residential SOPs (US EPA, 1997, section 2.3.4).
[b] From the RAGS document (U.S. EPA, 2004). There is not an activity specific-surface area weighted adherence factor for scouting with potential soil contact. Considering that diazinon is applied in the early growth season and the onion seedlings and crown areas of the berry plants are the areas for inspection, commercial/industrial gardeners (adults) was selected as a central tendency (i.e., typical) soil contact activity and the high-end weighted adherence factor (i.e., 95th percentile) for that activity (0.5 mg/cm^2) was used.
[c] Surface area of exposed skin (head, hands, forearms). Value from the RAGS document (U.S. EPA, 2004).
[d] Dermal exposure (µg/kg bw/day) = concentration in soil (µg a.i./mg soil) × adherence factor (0.5 mg soil/cm^2-event) × conversion factor (1 x 10^{-3} g/mg) × surface area (cm^2) × number of events/day × dermal absorption factor /body weight (80 kg). Based on the US EPA RAGS guidance document recommendations, a single event will be assumed. A dermal absorption (DA) factor of 50% was applied.
[e] Based on a $BMDL_{20}$ of 278 µg/kg bw/day and a target dermal MOE of 100.
[f] The proposed Restricted Entry Interval (REI) is the point in time when the target MOE of 100 was achieved

Appendix VII Label Amendments for Products Containing Diazinon

The following uses must be removed from product labels:

Control of adult root maggots in rutabaga and turnip

PRECAUTIONS

The following statements are required for wettable powder in water soluble packaging formulation:

DO NOT apply more than 30 kg active ingredient per person in a day. Mixers/loaders must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear. Applicators using groundboom equipment with a closed cab must wear coveralls over a long-sleeved shirt, long pants, socks and shoes. Wear chemical-resistant gloves when leaving the cab for cleanup and repair.

DO NOT open or puncture water soluble bag for any reason.

The following statements are required for emulsifiable concentrates:

Mixers/loaders must use a closed mechanical transfer loading system for liquid products. DO NOT handle more than 28 kg active ingredient per person in a day. Mixers/loaders must wear chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear. Applicators using groundboom equipment with a closed cab must wear coveralls over a long-sleeved shirt and long pants, socks and shoes. Wear chemical-resistant gloves when leaving the cab for cleanup and repair.

Open mixing/loading of emulsifiable concentrate product is prohibited

DIRECTIONS FOR USE

The following statements are required

Use on onion is limited for control of onion maggot larvae only and application in furrow at the planting or sowing time. DO NOT apply more than one application per year.

Uses on blackberry, loganberry and raspberry are limited for control of raspberry crown borer only and application at the time when new canes reach 10 cm height. DO NOT apply more than one application per year.

Uses on rutabaga and turnip are limited for control of root maggot larvae only and application at the seedling stage. DO NOT apply more than two applications per year.

RESTRICTED-ENTRY INTERVAL

The appropriate end-use product labels must include the following statement:

> DO NOT enter or allow worker re-entry into treated areas during the restricted entry intervals to conduct activities listed in the following Table.

Crop	Activity	Restricted-entry Interval
Onion	All activities	12 hours
Blackberry, loganberry and raspberry	All activities	12 hours
Rutabaga and turnip	Non-foliar contact scouting	12 hours
	Foliar contact scouting	25 days
	Thinning and hand weeding	15 days
	Handset irrigation	45 days
	All other activities	12 hours

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